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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/728,423

12/01/2000

Michael Houghton

1618.003

3252

27476

7590

06/15/2005

Chiron Corporation

Intellectual Property - R440

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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,423

Applicant(s)

HOUGHTON ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6 and 8-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 8-27 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the paper filed 7 February 2005.

Claims 1, 3-6, and 8- 27 are under consideration.

Rejections Withdrawn

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1- 27 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the metes and bounds required for "not secreted" are.

Applicant has amended the claims to require specific sequences and the rejection is withdrawn.

Claim Rejections - 35 USC § 102

Claims 1- 6, 8, 10, 12, and 15- 25 were rejected under 35 U.S.C. 102(a) as being anticipated by Fournillier *et al.*

Applicant has amended the claims and the rejection is withdrawn.

Claims 1- 5, 7, 10, and 14 were rejected under 35 U.S.C. 102(b) as being anticipated by Yanagi *et al.*

Applicant has amended the claims and the rejection is withdrawn.

Claim Objections

Claim 13 is objected to because of the following informalities: The term "PLG" should be spelled out the first time it is recited in the claims. Appropriate correction is required.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8-10, 14, 15, 17, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton *et al.* (EP0318216) and Fields.

The claims are drawn to a method of eliciting humoral immune response by administering HCV E2 or E1/E2 polynucleotide constructs.

Houghton *et al.* teach that the DNA of the envelope contain neutralizing epitopes (page 17, lines 13-27) and that this can be administered prophylactically or therapeutically (HCV infected or uninfected subjects) to make an antibody response, and administration be repeated (page 18).

Houghton *et al.* do not teach specific sequences of envelope.

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Fields Virology teaches that the envelope of HCV has an E1 and E2 polypeptides and regions encoding them (Figure 1) and teaches that p7 is found as a fusion with E2 (page 1038, column 2, top paragraph).

One of ordinary skill in the art at the time of invention would have been motivated to use the regions as defined in Fields to make the DNA composition to use in the method of Houghton *et al.* and that vaccine of Houghton *et al.* can be administered to infected or uninfected subjects.

Thus, it would be *prima facie* obvious to use the E2 and/or E1E2 regions as taught by Fields in the method of Houghton *et al.* to elicit a humoral immune response with the expectation of success because Houghton *et al.* teach that those regions will give rise to antibodies.

Claims 3 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton *et al.* (EP0318216) and Fields as applied to claims 1, 3-6, 8-10, 14, 15, 17, and 26 above, and further in view of Ishii *et al.* (previously cited).

The claims are drawn to a method of eliciting humoral immune response by administering HCV E2 or E1/E2 polynucleotide constructs. The added claims include limitations on the type of antibody and titer of antibody.

Houghton *et al.* (EP0318216) and Fields as discussed above, teach the invention essentially as claimed.

Houghton *et al.* (EP0318216) and Fields do not teach NOB antibodies or titers.

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Ishii *et al.* teach that antibodies to envelope (E2) give rise to NOB antibodies and that the titer can be at least 3000.

One of ordinary skill in the art at the time of invention would have been motivated to use the regions as defined in Fields to make the vaccine of Houghton *et al.* and that vaccine of Houghton *et al.* can be administered to infected or uninfected subjects.

Thus, it would be *prima facie* obvious to use the E2 and/or E1E2 regions as taught by Fields in the method of Houghton *et al.* to elicit a humoral immune response with the expectation of success because Houghton *et al.* teach that those regions will give rise to antibodies.

Claims 11-13, 16, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton *et al.* (EP0318216) and Fields as applied to claims 1, 3-6, 8-10, 14, 15, 17, and 26 above, and further in view of Nielson (AMPIS 1998, previously cited), or Singh *et al.*

The claims are drawn to a method of eliciting humoral immune response by administering HCV E2 or E1/E2 polynucleotide constructs. The added claims include limitations on types of DNA delivery methods and prime boost with DNA followed by polyprotein encoded by the nucleic acid.

Houghton *et al.* (EP0318216) and Fields as discussed above, teach the invention essentially as claimed.

Houghton *et al.* (EP0318216) and Fields do not teach the limitations of types of DNA delivery methods or prime boost with DNA followed by polyprotein encoded by the nucleic acid.

One of ordinary skill in the art at the time of invention would have been motivated to use art known modifications to the method for administering DNA. The use of agents to prepare the site for DNA inoculations is known in the art, such as cardiotoxin (see Nielson, AMPIS 1998, previously cited) as well as various methods to prepare DNA for inoculation, including different forms of microparticles, including PLG (Singh *et al.*, abstract). In the art of vaccination and immunization studies, boosting with protein after DNA vaccination is also known (Barnett *et al.*, abstract).

Thus, it would be *prima facie* obvious to use the E2 and/or E1E2 regions as taught by Fields in the method of Houghton *et al.* to elicit a humoral immune response with additional modifications of the method with the expectation of success because they are art know methods to improve DNA vaccinations.

Conclusion

No claim is allowed.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Myron G. Hill
Patent Examiner
~~August 9, 2004~~

6/8/05


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
6/13/05